

**Amendment and Response**

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Serial No.: 09/438,206

Confirmation No.: 9018

Filed: November 12, 1999

For: METHODS AND COMPOSITIONS FOR TREATING MAMMALIAN SPINAL CORD INJURIES

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**Remarks**

The Office Action mailed May 2, 2008, has been received and reviewed. Claims 23-25, 28, 30, 39, 40, and 44 having been amended, claims 22 and 38 having been canceled, without prejudice, and claims 45-49 having been added, the pending claims are claims 23-30, 39, 40, and 43-49. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for new claims 45 and 46 is found in canceled claims 22 and 38 and on page 12, lines 21-22 of the specification. New claims 47 and 48 are claims 30 and 40, respectively, rewritten in independent form to include the limitations of the claims from which they depend. Support for new claim 49 is found in claim 44. Applicants submit that no new matter is added with new claims 45-49.

**The 35 U.S.C. §103 Rejection**

Claims 22-29, 38, 39, and 44 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Shulman (U.S. Patent 4,599,354) and Edwards (U.S. Patent 4,369,769) (see Decision of the Board of Patent Appeals and Interference, mailed December 3, 2007). With the present Office Action claims 30, 40 and 43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Shulman and Edwards as applied to claims 22-29, 38, 39, and 44, and further in view of Potter. This rejection is respectfully traversed.

**New Claims 45 and 46 and Dependent Claims 23-30, 39, 40, 43, and 44**

Independent claims 22 and 38 have been canceled. As amended, claims 30, 40, and 43 (and claims 23-29, 38, 39, and 44) now depend from new claims 45 or 46. With the method of new claims 45 and 46, the effective amount of a C1-C10 polyalkylene glycol (claim 45) or polyethylene glycol (claim 46) administered is at least about 40% by weight in the composition. Applicants submit that Shulman in view of Edwards and further in view of Potter do not teach

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the administration of compositions comprising at least about 40% by weight of at least one C1-C10 or polyalkylene glycol or at least about 40% by weight of polyethylene glycol. Thus, Shulman in view of Edwards and further in view of Potter do not teach all elements of the methods of independent claims 45 and 46, dependent claims 30, 40, and 43, and dependent claims 23-29, 39, and 44.

Rather, Shulman teaches the administration of compositions comprising polyethylene glycol at concentrations of up to 10% by weight (see Shulman, col. 5, lines 7-10, and col. 6, lines 55-66) and exemplifies the administration of a composition of 2.3% PEG (see Shulman, col. 3, line 28 to col. 4, line 16). These limited teachings of Shulman are recognized by the Board of Patent Appeals and Interferences in its Decision mailed December 3, 2007 (see, pages 11 and 12). Both Potter and Edwards are silent as to administration of compositions comprising of at least one C1-C10 or polyalkylene glycol or polyethylene glycol.

Thus, Applicants submit that Shulman in view of Edwards and further in view of Potter do not teach all elements of the methods of new claims 45 and 46 and dependent claims 23-30, 39, 40, 43, and 44 (including dependent claims 30, 40, and 43). Thus, claims 23-30, 39, 40, and 43-46 are not obvious over Shulman in view of Edwards and further in view of Potter.

*New Claims 47-49*

Further, Applicants respectfully submit that new claims 47-49 (and claims 30, 40, and 43) are not obvious over under 35 U.S.C. §103(a) as being unpatentable over Shulman and Edwards and further in view of Potter in view of the evidence of unexpected results presented by the specification. With the present invention it has unexpectedly been discovered that treatment of an injured mammalian spinal cord with the potassium channel blocker 4-aminopyridine after treatment with a fusion agent, such as polyethylene glycol, results in synergistic repair of the spinal cord.

In this regard, Applicants direct the Examiner to page 13, line 26 to page 14, line 2 of the specification, which clearly teaches that "it has unexpectedly been observed that treatment of the

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injured mammalian spinal cord with a potassium channel blocker, such as 4-aminopyridine, after treatment with a fusion agent, such as polyethylene glycol, can result in synergistic repair of the spinal cord. For example, CAPs increase in conduction when both agents are used by a percentage greater than the sum of the percent increase in conduction of the CAPs when injured spinal cords are treated alone with either the fusion agent or the potassium channel blocker."

Further, the specification teaches "CAPs increase in coordination when both agents are used by a percentage greater than the sum of the percent increase in conduction of the CAPs when injured spinal cords are treated alone with either the fusion agent or the potassium channel blocker" (page 13, line 26 to page 14, line 2 of the specification). And, Applicants direct the Examiner to Example 2, entitled "Potassium Channel Blockade as an Adjunct to PEG-Mediated Recovery of Conduction" (page 24, line 17 to page 25, line 27 of the specification), Figure 6A-6C (depicting data from PEG/4-AP treated spinal cords), and the brief description of Figure 6 (page 6, lines 5-10 of the specification) for additional evidence demonstrating synergy.

Thus, treatment with both a fusion agent and the potassium channel blocker 4-aminopyridine is not merely additive. Rather, with the present invention it has unexpectedly been discovered that treatment of an injured mammalian spinal cord with the 4-aminopyridine, after treatment with a fusion agent, such as polyethylene glycol, results in the synergistic repair of the spinal cord. In view of these secondary considerations of nonobviousness, Applicants submit that claims 30, 40, 43, and 47-49 are not obvious under 35 U.S.C. 103(a) over Shulman and Edwards and further in view of Potter.

In view of the above discussion, the reconsideration and withdrawal of the rejection of claims 23-30, 39, 40, and 43-49 under 35 U.S.C. §103(a) as being unpatentable over Shulman and Edwards and further in view of Potter, is requested.

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**Summary**

It is respectfully submitted that the pending claims 23-30, 39, 40, and 43-49, are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the paper(s), as described hereinabove, are being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 4 day of August, 2008.

By: Sandy Truehart  
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